

REMARKS

Claims 11 and 14-16 are pending. Claims 1-10, 12-13 and 17-64 were previously cancelled. Claims 11 and 14-16 have been amended. The amendments were made to correct a typographical error and to improve matters of form. Accordingly, no new matter has been added.

Priority

The examiner states that the filing date of the instant application is considered to be 4/21/04 because none of the priority documents support the pending claims.

Applicants disagree.

U.S. Application Serial No. 60/503,596 is titled CpG aptamers. Pages 9 and 27 of this application discuss in general aptamers containing CpG motifs. Pages 10-26 disclose specific CpG motif containing aptamers, along with data from experiments using said aptamers. In particular, page 10 discloses three CpG motif containing aptamers that are encompassed by the pending claims: CpGARC124short, LongCpGARC124 and FullCpGARC124.

U.S. Application Serial No. 60/489,810 discloses aptamers containing CpG motifs on page 31. That same page also discloses a CpG motif that is similar to the claimed motif. Page 32 discloses data obtained from experiments using various aptamers containing CpG motifs.

U.S. Application Serial No. 60/474,133 discloses aptamers containing CpG motifs on page 68.

These three priority documents disclose aptamers containing CpG motifs, along with specific aptamers containing specific motifs, including aptamers that are encompassed by the pending claims.

Accordingly, applicants submit that the claimed invention is entitled to a priority date earlier than April 21, 2004.

Claim Objections

Claim 1 is objected to because the word “domains” is misspelled. In order to expedite prosecution, applicants have amended claim 1 to correct this typographical error. Accordingly, withdrawal of this objection is respectfully requested.

Claim 16 is objected to under 37 C.F.R. § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. More specifically, the examiner states that because claim 14 is a composition claim and not a method claim, the limitations as to how the cytotoxic agent is to be used are not considered to be further limiting. In order to expedite prosecution, applicants have amended claim 16 to delete the phrase “used alone or in combinations of one or more cytotoxic agents”. Applicants submit that amended claim 16 complies with 37 C.F.R. § 1.75(c) because the claim now relates to a group of cytotoxic agents. Accordingly, withdrawal of this objection is respectfully requested.

Rejection under 35 U.S.C. § 102

Claims 11 and 14-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lupold *et al.* (“U.S. Patent Application Publication No. 2002/0119473”).

Applicants respectfully disagree.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. M.P.E.P. § 2131. The elements

must also be arranged as required by the claim. M.P.E.P. § 2131. Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. M.P.E.P. § 2131.

Independent claim 11, as amended, and the claims that depend therefrom, are directed to an aptamer comprising a first nucleic acid sequence that binds to a first target and a second nucleic acid sequence that binds to a second target, wherein the second sequence is an immunostimulatory CpG motif that stimulates an immune response, wherein the CpG motif comprises the formula rCGyy, wherein “r” is a purine, “C” is cytosine, “G” is guanosine and “y” is a pyrimidine, and wherein the first sequence binds to a first target selected from the group consisting of PDGF, IgE, IgE Fcε R1, prostate-specific membrane antigen (PSMA), CD22, TNF-α, CTLA4, PD-1, PD-L1, PD-L2, FcRIIB, BTLA, transmembrane protein containing immunoglobulin and mucin-like domains (TIM-3), CD11c, B lymphocyte activating factor (BAFF), B7-X, CD19, CD20, CD25 and CD33.

Lupold *et al.* (“Lupold”) disclose aptamers to PSMA and methods for generating aptamers to PSMA. Lupold discloses a number of PSMA aptamers, including xPSM-A9 and xPSM-A10. Lupold also discloses that the PSMA aptamers are useful for the delivery of therapeutic compounds to tissues or organs expressing PSMA.

The claims require that the rCGyy CpG motif bind to a second target and, upon binding to the second target, stimulate an immune response. However, there is no disclosure in Lupold that the cited sequences within the PSMA nucleic acid ligands would actually bind to any target other than PSMA or that the cited sequences would bind to such target and stimulate an immune response. The presence of a shorter oligonucleotide sequence within a larger oligonucleotide molecule alone is not dispositive of the ability of that shorter oligonucleotide sequence to bind to a given target. As there is no teaching in Lupold regarding a CpG element, it cannot be assumed

that the CpG sequences cited by the Examiner would bind to a target and stimulate an immune response.

Furthermore, Lupold does not disclose aptamers containing CpG motifs and the benefits derived from having an immunostimulatory CpG motif. Even though Lupold discloses that PSMA aptamers are useful for the delivery of therapeutic compounds, such as immune enhancing substances, Lupold does not mention CpG motifs. Also, even though the A9 and A10 aptamers in Lupold each contain a nucleotide sequence that corresponds to the CpG motif in applicants' claims, Lupold still fails to mention CpG motifs in general and the specific motif in applicants' claims. Therefore, Lupold does not disclose each and every limitation of the claimed invention as arranged in the claim.

As discussed in *Net Moneyin, Inc. v. Verisign, Inc.* (CAFC 2008), the hallmark of anticipation is prior invention. Unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102. Applying this case to Lupold, Lupold does not disclose aptamers containing CpG motifs in general, the specific CpG motif in applicants' claims and the benefits derived from having an immunostimulatory CpG motif so Lupold does not show applicants' invention as arranged in the claim. By definition, Lupold cannot anticipate the claimed invention. Accordingly, withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

CONCLUSION

Applicants submit that claims 11 and 14-16 are now in allowable form. Accordingly, reconsideration of the objection and allowance of the claims at an early date are earnestly solicited.

If there are any questions regarding this Amendment and Response or if the undersigned can be of assistance in advancing the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,



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